

K935161 KERATIN PRIMARY ANTIBODYMar 22, 1996
875 days to decisionK935161 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k935161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lambda, Antigen, Antiserum, Control (DEH)
Date received	Oct 29, 1993
Decision date	Mar 22, 1996
Days to decision	875 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ventana Medical Systems, Inc.
Location	Tucson, AZ, US
Contact	STEPHEN TILLSON
Website	http://www.ventana.com/
510(k) history	48 submissions · 46 cleared · 1992-2024

Ventana Medical Systems, Inc. specializes in immunohistochemical staining reagents and antibody-based diagnostic solutions, with a manufacturing facility in Tucson, Arizona. The company develops primary antibodies and prediluted reagents for pathology laboratories and immunology applications. Ventana has received FDA 510(k) clearances from total submissions since 1992, establishing a strong regulatory track record in immunology devices. The company remains active, with its most recent clearance in 2024, demonstrating continued innovation in antibody-based diagnostic produ...
